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मानक

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“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

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“Step Out From the Old to the New”

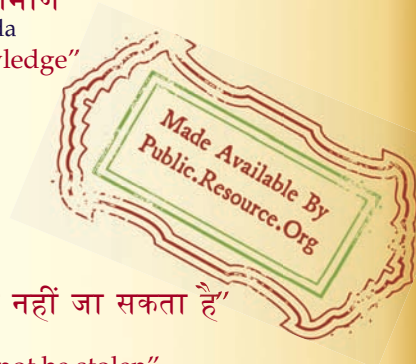
IS 5347-8 (1997): Requirements for orthopaedic implants,
Part 8: Forgeable and
cold-formed-cobalt-chromium-nickel-molybdenum-iron alloy
[MHD 2: Orthopaedic Instruments, Implants and Accessories]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक

अस्थि अन्तर्रोपणों की अपेक्षाएं

भाग 8 ठण्डे रूप से जड़ने योग्य कोबाल्ट-क्रोमियम-
निकल-मौलीब्डेनम-लोह मिश्रधातु

(पहला पुनरीक्षण)

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 8 FORGEABLE AND COLD-FORMED COBALT-CHROMIUM-NICKEL-
MOLYBDENUM-IRON ALLOY

(*First Revision*)

ICS 11.040.40

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BUREAU OF INDIAN STANDARDS
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NATIONAL FOREWORD

This Indian Standard (Part 8) (First Revision) which is identical with ISO 5832-7 : 1994 'Implants for surgery - Metallic materials - Part 7 : Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards, on the recommendation of Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1984 as dual number standard. Its first revision has been issued to incorporate the modifications effected in the second edition of ISO 5832-7 brought out in 1994. In this revised version chemical composition of the material has been redefined. Percentage range of manganese has been changed from the existing 1.0 to 2.0 to 1.0 to 2.5. Percentage limits of other important elements that is silicon, phosphorus and sulphur have also been added. References have been made to the latest ISO Standard for tensile testing. Values of mechanical properties, that is tensile strength, proof stress, percentage elongation in the spring temper condition have been included.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 643 : 1983	IS 4748 : 1988 Method for estimating average grain size of metals (<i>first revision</i>)	Technically Equivalent
ISO 4967 : 1979	IS 4163 : 1982 Method for determination of inclusion content in steel by macroscopic method (<i>first revision</i>)	do
ISO 6892 : 1984	IS 1608 : 1995 Mechanical testing of metals — Tensile testing (<i>second revision</i>)	do

This Indian Standard has been issued in 12 parts. Other parts of this standard are:

- Part 1 General requirements
- Part 2 Wrought stainless steel
- Part 3 Unalloyed titanium
- Part 4 Wrought titanium 6-aluminium 4-vanadium alloy
- Part 5 Cobalt-chromium-molybdenum casting alloy
- Part 6 Wrought cobalt-chromium-tungsten-nickel alloy
- Part 7 Wrought cobalt-nickel chromium-molybdenum alloy
- Part 9 Ceramic materials based on alumina
- Part 10 Ultra-high molecular weight polyethylene, powder form
- Part 11 Ultra-high molecular weight polyethylene, moulded form
- Part 12 Wrought cobalt-nickel-chromium-molybdenum-iron alloy

Parts 13, 14 and 15 of this standard are also under preparation and will be published shortly.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2:1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 8 FORGEABLE AND COLD-FORMED COBALT-CHROMIUM-NICKEL- MOLYBDENUM-IRON ALLOY

(*First Revision*)

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy for use in the manufacture of surgical implants.

NOTE 1 The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with those specified in this part of ISO 5832.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5832. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5832 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 643:1983, *Steels — Micrographic determination of the ferritic or austenitic grain size*.

ISO 4967:1979, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams*.

ISO 6892:1984, *Metallic materials — Tensile testing*.

3 Chemical composition

The heat analysis of the alloy when determined as specified in clause 6 shall comply with the chemical composition specified in table 1. The analysis of samples taken from products manufactured from the alloy shall also comply with table 1.

Table 1 — Chemical composition

Element	Compositional limits, % (m/m)
Cobalt	39 to 42
Chromium	18,5 to 21,5
Nickel	14 to 18
Molybdenum	6,5 to 8
Manganese	1 to 2,5
Silicon	1 max.
Carbon	0,15 max.
Phosphorus	0,015 max.
Sulfur	0,015 max.
Beryllium	0,001 max.
Iron	Balance

4 Microstructure

4.1 Grain size

The microscopic structure shall be uniform. The grain size, determined as specified in clause 6, shall be no coarser than grain size No. 5.

4.2 Inclusion content

The non-metallic inclusion content of the alloy, determined as specified in clause 6, shall not exceed the limits given in table 2.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content thin ¹⁾
A — Sulfides	1
B — Aluminates	3
C — Silicates	1
D — Oxides, globular	3
1) There shall be no thick inclusions.	

5 Mechanical properties

The mechanical properties, determined as specified in clause 6, shall be in accordance with the requirements of table 3.

6 Test methods

The test methods to be used in determining compliance with the requirements of this part of ISO 5832 shall be those given in table 4.

Table 3 — Mechanical properties

Condition	Tensile strength min. MPa	Proof stress of non-proportional elongation min. MPa	Percentage elongation min. %
Annealed	950	450	65
30 % cold-worked	1 450	1 300	8
Spring temper ¹⁾	1 650	1 400	1
1) for specific applications.			

Table 4 — Test methods

Requirement	Relevant clause or subclause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Inclusion content	4.2	ISO 4967
Grain size	4.1	ISO 643
Mechanical properties Tensile strength Percentage elongation Proof stress of non-proportional elongation	5	ISO 6892

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards Monthly Additions'.

This Indian Standard has been developed from Doc: No. MHD 2 (2679).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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